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REPORT TO THE CONGRESS

093790



BY THE COMPTROLLER GENERAL OF THE UNITED STATES

Management Of The Licensing Of Users Of Radioactive Materials Should Be Improved

Nuclear Regulatory Commission

The Nuclear Regulatory Commission regulates, through a licensing and inspection program, about 6,000 radioactive material users and has transferred to 25 States authority to regulate 8,000 additional users.

The report shows that the Commission needs to improve the management of its licensing program by

- --requiring license applicants to describe detailed radiation safety programs,
- --improving communications between its separate licensing and inspection staffs, and
- --improving management reviews of licensing actions for uniformity and completeness.

The Commission should encourage the 25 States to effect similar improvements in their licensing programs

093796



COMPTROLLER GENERAL OF THE UNITED STATES WASHINGTON, D.C. 20548

B-164105

To the President of the Senate and the Speaker of the House of Representatives

This report discusses the need for management improvements in the Nuclear Regulatory Commission's program for licensing users of radioactive materials.

We made our review pursuant to the Budget and Accounting Act, 1921 (31 U.S.C. 53), and the Accounting and Auditing Act of 1950 (31 U.S.C. 67).

We are sending copies of this report to the Director, Office of Management and Budget, and to the Chairman, Nuclear Regulatory Commission.

Comptroller General of the United States

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ABBREVIATIONS

AEC Atomic Energy Commission

GAO General Accounting Office

NRC Nuclear Regulatory Commission

COMPTROLLER GENERAL'S REPORT TO THE CONGRESS

MANAGEMENT OF THE LICENSING OF USERS OF RADIOACTIVE MATERIALS SHOULD BE IMPROVED Nuclear Regulatory Commission

DIGEST

GAO is making several recommendations to the Nuclear Regulatory Commission aimed at increasing the management effectiveness of its program, and the programs of State governments, for licensing users of radioactive materials.

If these recommendations are accepted and put into effect, the public health and safety should be better protected from radiation hazards.

As of December 31, 1974, there were 8,253 Commission-issued licenses. In addition, 25 States have been authorized to regulate users of radioactive materials; as of the same date there were 10,142 active Stateissued licenses. (See p. 1.)

The basic premise of regulating the use of radioactive materials is that unnecessary exposure to radiation should be avoided.

In fiscal year 1974 Commission inspectors found 2,073 violations of regulations and license conditions in 827, or 53 percent, of the 1,551 inspections.

In 562 inspections, 1,155 violations were major enough to have actually or potentially resulted in radiation exposure to individuals or in release of radiation in excess of permissible limits. (See p. 5.)

Radioactive material users include colleges and universities, medical institutions, and industrial firms. The types of licenses described in this report do not include licenses to construct or operate nuclear power reactors.

The Commission does not systematically require prospective users of radioactive

materials to describe, in their applications for licenses, the radiation protection procedures and administrative controls they intend to use so that their operations will be safe and will comply with regulations.

In its inspections the Commission found that:

- --Many licensees had not developed procedures and controls necessary to comply with regulatory requirements. (See pp. 8 to 10.)
- --The users thought by the Commission to be best able to use radioactive materials safely had experienced highest rates of noncompliance, particularly in failing to develop adequate radiation safety programs. (See pp. 10 to 13.)

Applications for licenses are seldom denied. (See p. 3.)

Most applicants for licenses have never been inspected. (See p. 18.)

The Commission's licensing staff does not:

- --Routinel Teview inspection histories of applicants for license changes before issuing amendments or renewals. (See pp. 19 and 20.)
- --Use inspection results to identify areas needing improvement. (See pp. 20 and 21.)
- --Have a standard license application review program so that application evaluations are consistent and complete and so that the bases for licensing actions can be documented. (See p. 30.)
- --Evaluate systematically the propriety of licensing actions. (See p. 30.)

The Commission also needs closer communication between its licensing and inspection staffs. Although inspectors have identified weaknesses in the regulatory program which they believe could be strengthened through improved licensing practices, they have not effectively notified the licensing staff of these weaknesses. (See pp. 18 and 21.)

Commission officials agreed to examine the degree of reliance placed on radioactive material users' qualifications and the degree of detail required on applications concerning radiation safety controls and procedures. The Commission also has taken steps so that (1) inspection results are considered by those who approve the licenses and (2) evaluations of applications are uniform and complete. (For further details on the Commission's comments, see pp. 17, 26, and 30 and app. I.)

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CHAPTER 1

INTRODUCTION

Under the Atomic Energy Act of 1954, as amended (42 U.S.C. 2011-2296), and title II of the Energy Reorganization Act of 1974 (42 U.S.C. 5841), the Nuclear Regulatory Commission (NRC) is responsible for regulating the possession, use, and disposal of radioactive materials 1/to protect public health and safety against radiation hazards. NRC discharges its responsibility through a licensing and inspection program. The Office of Nuclear Material Safety and Safeguards licenses radioactive material users; the Office of Inspection and Enforcement conducts inspection and enforcement activities.

NRC's regulations governing the possession, use, and disposal of radioactive materials are in title 10 of the Code of Federal Regulations. The regulations set out general licensing requirements for byproduct, source, and special nuclear materials and specific requirements for certain uses of radioactive materials, such as in medicine. Licensees are also required to comply with specific conditions 2/ included in their licenses.

Radioactive material licenses are required for manufacturing nuclear fuel for reactors and for industrial, commercial, medical, and educational uses of radioactive materials. This type of license is not for constructing or operating nuclear power reactors and facilities for processing used nuclear fuel. As of December 31, 1974, there were 8,253 active NRC-issued material licenses held by 6,310 licensees.

Under section 274 of the Atomic Energy Act of 1954, as amended, NRC has authorized 25 States to license radio-active material users operating in those States. Examples of regulatory responsibilities which may not be transferred

^{1/}Source material (uranium and thorium), byproduct material (radioisotopes produced in nuclear reactors), and special nuclear material (plutonium and enriched uranium). NRC does not regulate other materials which emit radiation that are either naturally occurring, such as radium, or produced other than by reactors, such as by accelerators.

^{2/}License conditions are included in licenses to place specific requirements on licensees, including those the regulations may not cover.

include export and import licensing and disposal into the ocean. As of December 31, 1974, there were 10,142 active State-issued licenses held by 8,009 licensees.

LICENSING RADIOACTIVE MATERIAL USERS

NRC's radioactive material licenses are valid for 5 years and are renewable. In addition, licensees may have their licenses amended to change the authorized forms, possession limits, uses, or users of radioactive materials. New licenses, renewals, and amendments completed during fiscal year 1974, by major types of licenses, are shown below.

| | New | | Amend- | |
|--------------------------|--|----------|--------|-------|
| Type of license | <u>licenses</u> | Renewals | ments | Total |
| Byproduct material: | | | | |
| Academic | 47 | 125 | 156 | 328 |
| Medical | 68 | 608 | 4,185 | 4,861 |
| Industrial | | • | · | - |
| radiography | 6 | 68 | 95 | 169 |
| Measuring systems | 110 | 376 | 469 | 955 |
| Research and | | | | |
| development | 13 ' | 140 | 227 | 380 |
| All others | 89 | 172 | 244 | 505 |
| | ************************************** | | | |
| Total | 333 | 1,489 | 5,376 | 7,198 |
| | | | | |
| Source material | 95 | 44 | 46 | 185 |
| Choosial musloar | | | | |
| Special nuclear material | 177 | 100 | 218 | 495 |
| | | | | |
| Total | 605 | 1,633 | 5,640 | 7,878 |

The NRC licensing staff reviews applications to determine whether the proposed programs can be conducted safely and within regulation requirements. They evaluate such aspects as the

⁻⁻identity, maximum possession limit, and intended use
 of the radioactive material;

⁻⁻training and experience of the individual users and persons responsible for radiation safety;

⁻⁻radiation detection instruments, personnel-monitoring devices, and facilities to be used; and

--radiation protection procedures and administrative controls.

If the licensing staff believes that there are deficiencies in an application, the applicant is given the opportunity to submit additional or clarifying information. If this information is not satisfactory, NRC may formally deny the applicant a license. However, this is seldom done-perhaps five times a year, according to a senior licensing official.

Most applications are evaluated and licenses are issued without inspections of applicants' facilities, equipment, and radiation protection programs. However, for licensees handling large quantities of radioactive materials, such as nuclear fuel fabricators, prelicensing inspections are a part of the licensing review.

An NRC licensing-program official delegated authority to issue licenses to 11 of the 13 staff members. Licenses for applications reviewed by the two other staff members are issued by senior staff members.

INSPECTING USERS

NRC has five regional offices in the United States that inspect licensees in their assigned geographic areas. The major part of each region's workload is inspecting the construction and operation of nuclear power reactors; less manpower is assigned to inspect radioactive material licensees. For example, in 1 region, only 6 of the 70 professional staff members (about 9 percent) are available to inspect approximately 3,000 material licensees.

NRC has developed a five-category priority inspection system on the basis of the theory that inspection frequency should relate to potential public hazards associated with licensed activities.

NRC inspectors conducted 1,551 material license inspections during fiscal year 1974. The following table lists the number of licenses and inspections, by inspection priority.

| <u>Priority</u> | Licenses (note a) | Number of inspections | <pre>Inspection/license ratios (note b)</pre> |
|-----------------|-------------------|-----------------------|---|
| I | 59 | 146 | 2.47 |
| II | 521 | 316 | .61 |
| III | 1,244 | 326 | .26 |
| IV | 3,229 | 574 | .18 |
| V | 3,102 | 189 | .06 |
| | 8,155 | 1,551 | |

 \underline{a}/As of June 30, 1974.

 $\underline{b}/\mathtt{Some}$ licenses were inspected more than once.

CHAPTER 2

PROGRAM NEEDS A STRONGER LICENSING POLICY

NRC does not systematically require prospective users to describe, in their applications, the procedures and controls they intend to use so that their operations will be safe and will comply with regulations. NRC receives information from applicants on the training and experience of the persons who will supervise the use of the radioactive materials, the facilities and equipment to be used, and the radiation protection procedures and administrative controls to be implemented. NRC believes, however, that, when its regulations are clear and specific and methods for attaining compliance are well known, it is appropriate to rely on applicants' qualifications rather than obtain and evaluate detailed procedures and controls.

NRC should obtain and evaluate descriptions of such applicants' procedures and controls to better insure that radioactive materials will be safely used. Its past procedures have contributed to the high frequency of violations found in license inspections.

NEED TO SYSTEMATICALLY EVALUATE PROCEDURES AND CONTROLS FOR INSURING COMPLIANCE WITH REGULATIONS

The basic premise underlying radioactive material regulations is that unnecessary radiation exposure should be avoided. In fiscal year 1974 inspectors found 2,073 violations in 827--53 percent--of the 1,551 inspections. In 562 inspections, 1,155 violations were major enough to have actually or potentially resulted in radiation exposure to individuals or in release of radiation in excess of permissible limits; for example, excessive levels of radiation in areas next to locations where radioactive materials are used or stored.

We reviewed the license and inspection files of 36 licenses on which 120 major violations were found during fiscal year 1974. These licenses are not statistically representative of all licenses issued by NRC, most of which have never been inspected. They were selected because the violations were the type most frequently found in the 562 fiscal year 1974 inspections having major violations.

| | Major violations | | | |
|--|------------------|-------|--------|-----|
| Sections of regulations | | | Selec | ted |
| for which violations were cited | All lice | nses | licen | ses |
| Standards for protection against radiation: | | | | |
| Permissible doses, levels, | | | | |
| and concentrations | 64 | | 5 | |
| Radiation surveys | 245 | | 39 | |
| Procedures for receiving | | | | |
| and opening packages | 52 | | 6 | |
| Security and storage of | | | | |
| materials | 33 | | 7 | |
| Posting and labeling | | | | |
| controls | 29 | | 1 | |
| Waste disposal | 7 | | 1 1 | |
| Other | 7 | 437 | - | 59 |
| o che i | | 437 | | 33 |
| Notices, instructions, and reports to workers; in- | | | | |
| spections | | 81 | | 13 |
| Safety requirements for | | - | | -0 |
| radiographic operations | | 114 | | 4 |
| Other regulations . | | 152 | | 11 |
| License conditions | | 371 | | 33 |
| Trense Conditions | | | | |
| Total | | 1,155 | | 120 |
| | | =_=== | | |

For 77 of the 120 violations, including 53 of the 59 violations of standards for protection against radiation, licensees had not described in their applications—nor had NRC's licensing staff obtained and evaluated before issuing the licenses—detailed radiation protection procedures and administrative controls. Eight violations resulted from the licensees' failure to follow radiation protection procedures described in their applications. For the remaining 35 violations, licensees either had not complied with specific conditions of their licenses or had conducted unauthorized activities.

For 10 of the 36 licenses, we asked the NRC licensing staff if it should have obtained and evaluated detailed descriptions of the radiation protection procedures and controls applicants were to implement for that part of their radiation safety programs in which major violations were found. For these 10 licenses--4 medical, 5 academic, and 1 industrial--inspectors had found 39 major violations.

| Type of violation | Major | violations |
|--|-------------------------|-------------|
| Standards for protection against radiation: Permissible doses, levels, | | |
| and concentrations | 5 | |
| Radiation surveys | 15 | |
| Procedures for receiving and | | |
| opening packages | 1 | |
| Security and storage of | | |
| materials | 3 | |
| Waste disposal | 1 | 25 |
| Notices, instructions, and reports | | |
| to workers; inspections | | 7 |
| Other regulations | $(x,y) \in \mathcal{X}$ | 3 |
| License conditions | | 4 |
| Hicense conditions | | mails orman |
| Total | | 39 |

In response to questions related to 29 of the violations, NRC licensing staff stated, in December 1974, that:

- --In the area where two of the violations occurred, additional information would be required for evaluating the applications.
- --In the area where five of the violations occurred, the information provided by applicants was sufficiently detailed.
- --In the area where 22 of the violations occurred, it was not necessary to obtain and evaluate detailed radiation procedures and controls.

In licensing radioactive material users, the NRC licensing staff stated:

"Specifically, the Commission must determine that the applicant is properly qualified by virtue of training and experience, facilities and equipment, radiation safety procedures and administrative controls to conduct the proposed activities in accordance with the [NRC] regulations and license conditions. In making the determination, the Licensing staff must take into account the type, form, quantity and proposed use of the byproduct material being requested. As the above-cited factors vary from one type of isotope user to another, the nature and detail of information requested on radiation safety will also vary.

"An important element of the review is the exercise of technical judgment as to the degree of detail to be elicited from the applicant in specific areas in order to demonstrate that the various regulatory requirements will be met. In many cases the regulatory requirements are clear and specific and there are known, established methods for meeting the requirements. Detailed supporting information is not necessary in these instances. Rather, it is appropriate to put reliance on the applicant's qualifications for assurance that the requirements will be met.

"In the final analysis, the Licensing staff must appropriately balance all of the above factors and arrive at a technical judgment as to whether there is reasonable assurance that the applicant has demonstrated he will be able to conduct the proposed activities in accordance with the regulations and license conditions."

The licensing staff believes that it is not always necessary to evaluate detailed descriptions of applicants' radiation protection procedures and administrative controls, especially when regulatory requirements are clear and specific and methods for compliance are well known. In these instances the licensing staff believes it is appropriate to rely on applicants' qualifications—training and experience.

The need to obtain and evaluate detailed descriptions of applicants' procedures and controls was demonstrated by material license inspection results which indicated that:

- --Many licensees had not developed and carried out procedures and controls necessary to comply with regulatory requirements.
- --The users thought best able to use radioactive materials safely, and on whose qualifications NRC's licensing staff relied heavily, had experienced the highest rates of noncompliance, particularly in failing to develop adequate radiation safety programs.

Licensees did not develop adequate procedures and controls

For 74 of the 77 violations where detailed procedures had not been described in documents submitted during the

application process, the licensees developed procedures and/or controls after being cited for the violations. In many cases these procedures or controls were developed after the licensees had been conducting their programs for a long time.

For 14 of 36 licenses reviewed, the inspections where the violations were found were initial ones and occurred months after the licenses were granted—an average of 15 months for 6 academic licenses, 24 months for 5 medical licenses, and 19 months for 3 industrial licenses.

The inspectors did not always document specific reasons why licensees failed to develop and carry out adequate radiation protection procedures before the inspections occurred. The reasons cited included:

- --Licensees did not know how to carry out required procedures.
- --Licensees were not familiar with, or misinterpreted, the regulations and therefore were not aware that the procedures were necessary.
- --Licensees' procedures were inadequate and did not comply with the regulations.

If the applicants had been required to describe detailed procedures and controls as part of their applications, the licensing staff would have been assured that the applicants were capable of translating regulatory requirements into radiation protection procedures and controls adequate for their proposed programs. We noted that many requirements were stated in general terms and did not specify the actions licensees should take. For example, one stated that "Each licensee shall make or cause to be made such surveys as may be necessary for him to comply with the regulations in this part."

Surveys may include radiation detection by instruments designed for this purpose, mathematical calculations, physical inventories, or analyses of radioactivity in body wastes. Survey methods or combinations of methods vary with the types of materials, their physical and chemical forms, and the quantities possessed. Surveys are important because radiation levels cannot be determined unless properly measured. Timely and effective surveys help insure that persons working with, or in the vicinity of, radioactive materials do not receive radiation exposures exceeding permissible limits or that radioactive materials released to the atmosphere do not exceed permissible limits.

Over 20 percent of the major violations noted in fiscal year 1974 were survey violations. For 36 of the 39 survey violations reviewed, licensees had not described detailed survey procedures.

In September 1973 an inspector found that an academic licensee had failed to survey concentrations of radioactivity where a specific radioactive material was routinely handled and had failed to survey the radioactivity of gases released to the atmosphere. This was the first complete inspection since the licensee was authorized to use this material in March 1967. In its application the licensee had not addressed the subject of surveying airborne concentrations of radioactivity in the laboratory or of surveying gaseous releases.

The licensee told inspectors that, to correct the violations, it was developing detailed procedures to routinely survey airborne concentrations of radioactivity in the laboratory, to survey gaseous releases, and to take thyroid assays (a method of evaluating an individual's ingestion of the radioactive material).

In December 1973 the licensee applied to renew the license. NRC's licensing staff asked the licensee to describe its "methods for ensuring that the proper precautions are taken during the use of" this radioactive material. The licensee described the detailed procedures developed after the inspection.

In October 1974 an inspector verified that the licensee had corrected the procedure; no violations were noted in that inspection.

Reliance on users' qualifications is inappropriate

NRC's licensing staff has relied heavily on users' qualifications for medical and academic licenses rather than obtain and evaluate detailed descriptions of radiation protection procedures and controls. The highest rates of noncompliance, however, occur in such licenses. The following table shows the frequency and type of violations found during fiscal year 1974 inspections and the number of each type of license as of June 30, 1974.

| | | Inspections | | | | |
|---|------------------------------|------------------|-----------------------------|--|--|--|
| Type of license | Licenses as of 6-30-74 | <u>Total</u> | With one or more violations | Percent where violations <u>existed</u> | | |
| Academic: Broad (note a) | 15 | 6 | 5 | 83 | | |
| Specific (note b) | 584 | 104 | <u>75</u> | 72 | | |
| | 599 | 110 | 80 | 73 | | |
| Medical: Broad (note a) Specific | 87 | 48 | 36 | 75 | | |
| (note b) Teletherapy | 2,102 469 | 324 118 | 207 72 | 64 61 | | |
| | 2,658 | 490 | 315 | 64 | | |
| Industrial radio- graphy Other industrial Source material Special nuclear | 335 3,384 447 | 193 477 58 | 106 212 21 | 55 44 36 | | |
| material | 732 | 223 | 93 | 42 | | |
| | 4,898 | 951 | <u>432</u> | 45 | | |
| Total | 8,155 | 1,551 | <u>827</u> | 53 | | |

a/Broad licenses authorize the possession and use of various quantities and types of radioactive materials under the supervision of licensees' radioisotope committees. Individual users are not named on the licenses but are designated by the committees.

We reviewed 13 specific academic licenses and 9 specific medical licenses. The complexity of the 22 licenses varied from a small quantity of 3 materials authorizing a single user to 3 licenses authorizing multiple users of over 25 materials. In fiscal year 1974 inspectors found 84 major violations of these 22 licenses. For 62 violations, the licensees did not describe in their applications, nor had NRC's licensing staff obtained and evaluated before issuing

b/Specific licenses authorize the possession and use of specified quantities and types of radioactive materials by or under the supervision of users named in the licenses.

the licenses, detailed procedures and controls. For a number of such violations on ll academic licenses held by a university, inspectors found that many of the authorized users were not familiar with the NRC's regulations and were not conducting, or did not know how to conduct, proper radiation surveys. One authorized user was not aware that his survey instrument could not detect the radiation contamination which might be present as a result of his major operation. Other authorized users were not familiar with the regulations. In a memorandum summarizing the inspection results of ll licenses held by this licensee, the inspector said:

"Personnel all stated that they received no instructions in the applicable provisions of Commission [NRC] regulations, the licenses involved, etc. Many were totally unfamiliar with common survey techniques and the reasons for taking them. The violations noted will emphasize the lack of knowledge in many vital areas."

NRC's inspection staff compared the frequency of noncompliance for calendar year 1973 inspections of five types of licenses. These included broad industrial and academic licenses, in-plant and field radiography 1/licenses, and institutional (broad and specific) medical licenses. For each inspection region, the frequency of noncompliance was generally higher for institutional medical licenses than for other types of licenses. The study concluded that more frequent inspections of medical licenses were necessary because medical programs tended to have less formal and unstructured radiation protection programs.

One inspection region also analyzed noncompliance data for specific academic licenses. This region found that both the frequency of noncompliance and the number of violations for each inspection were highest for broad and specific academic licenses and medical licenses. The region attributed the higher frequencies to less organizational stability for such users compared with industrial users.

Although the other four regions did not compile compliance data for specific academic licenses, they had conducted 37 of the 104 specific academic license

^{1/}The examination of the structure of materials by nondestructive methods, using a sealed source of byproduct material.

inspections in fiscal year 1974 and found 1 or more violations in 26, or about 70 percent, of these inspections.

NRC inspection officials have suggested that stronger licensing action requiring applicants to develop and describe in applications detailed procedures and controls could assist in reducing violations. For example, one region said that:

"* * * fewer violations are routinely found for licensees whose licenses require a more structured safety program; therefore, the argument follows that more realistic licensing requirements on medical licensees as to procedures required to be set forth and followed could improve the performance by these licensees. In other words, the best solution is to license only those persons who reasonably demonstrate in their application that the program is adequate to meet the Commission's [NRC's] requirements, rather than our resources being diluted by increased inspection effort." (Underscoring supplied.)

Another region suggested that:

"* * * licensing review their procedures and criteria based upon inspection histories. For example, licenses issued to institutions with other licenses should not rely on the user concept but should require management awareness and audits, centralized radiation safety services and conservative waste disposal procedures." (Underscoring supplied.)

The licensing staff believes, however, that it is not always necessary to evaluate applicants' detailed procedures and controls, especially when regulatory requirements are clear and specific and methods for compliance are well known. In these instances the licensing staff believes it is appropriate to rely on applicants' qualifications—training and experience—for insurance of compliance. This position contrasts sharply with NRC's expectations of agreement States' operations.

Section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021), as amended, authorized the Atomic Energy Commission (AEC) to transfer to a State the authority to regulate by product and source materials and special nuclear materials in limited quantities. As of December 31, 1974, AEC had entered into agreements with 25 States. This authority and the existing agreements were transferred to NRC by the Energy Reorganization Act of 1974.

Section 274j of the Atomic Energy Act of 1954 (42 U.S.C. 2021(j)), as amended, authorizes NRC to terminate an agreement if it finds that a State's program is not adequate to protect public health and safety. Until 1965 AEC relied on informal information exchange and periodic meeting and trained State personnel to promote and evaluate the continued adequacy and compatibility of State programs.

In 1965, to avoid dual regulation by it and the Department of Labor, 1/AEC committed itself to making formal, annual determinations that State programs were adequate to protect public health and safety and were compatible with AEC's program. NRC continues this procedure. In making these determinations NRC periodically visits each State, to evaluate its licensing, inspection, and enforcement activities. Officials making these visits review licenses and supporting applications; evaluate inspection reports and enforcement actions; accompany State inspectors during inspections; and obtain information on overall program administration, such as budget data and personnel qualifications and training.

We reviewed evaluations of 24 State licensing programs conducted between October 1972 and December 1974. NRC's licensing staff assisted in 13 of these evaluations.

For 11 of the 24 evaluations, including 7 in which the licensing staff participated, the licensing programs were criticized for not obtaining and evaluating applicants' procedures before issuing licenses and license amendments. Following are typical comments from reports on three State licensing programs evaluated by NRC's licensing staff.

"Several state license files were reviewed. It was noted that the license backup information documented in the files was not sufficient in many cases to support the uses authorized by the license. * * * While inspections conducted soon after license issuances were used to gather additional information and obtain corrective action on problems noted, it is suggested that information on personnel, facilities, equipment, and

^{1/}Between 1962 and 1965 Labor amended its safety regulations issued under the Walsh-Healey Act (41 U.S.C. 35) to impose radiation safety requirements on employers having Federal Government contracts over \$10,000. In 1965 Labor published a proposed amendment to its safety regulations which would have resulted in dual surveillance of State radiation control programs with the former AEC.

procedures obtained from the applicant be documented and evaluated prior to license issuance to help assure that operations are started safely and in compliance with the regulations." (Underscoring supplied.)

"Our review of the evaluation of licenses and devices indicated in some cases a lack of depth and comprehensiveness needed to ensure complete consideration of all aspects of health and safety. We recommend that more time and emphasis be placed on evaluation of licenses and devices. This will decrease dependency on inspection to ensure that the licensee is knowledgeable, has adequate facilities, and is otherwise capable to conduct activities with radioisotopes in a safe manner."

(Underscoring supplied.)

"The main thrust of our comments regarding industrial and academic licenses was that in several cases the licensee did not submit appropriate radiation safety procedures. While these may vary substantially due to the scope of the program, we believe that review of such procedures is an essential element of the licensing process." (Underscoring supplied.)

NRC's reports on State programs contained many references to the need to obtain and evaluate the adequacy of licensees' procedures and controls to insure regulatory compliance.

"* * * specific instructions [for student usage]
is needed."

"There were no clear and specific instructions to students for use and handling of the radio-active materials."

"In regard to instructions to students regarding health and safety procedures, it was noted that the application only made the statement that 'instructions will be given.' * * * [The State license reviewer] will obtain the appropriate information as soon as possible."

"The radiation safety procedures including instructions for personnel were poor. The procedures were old and contained a great number of references to regulations but no instructions on how to comply with the regulations."

"The description of the radiation protection was too general for the scope of the program. The information was not specific with respect to handling of generators, performance of surveys, storage, handling, and use of material, etc."

"A statement in the application 'A survey has been made of all areas of the department in which exposure above normal background could result. Maximum possible doses have been calculated and recorded. With present sources and precaution measures, no overexposures can result' is a conclusion and is not an adequate description of the radiation protection program."

"There was no statement in the application concerning disposal of radioactive wastes."

"The radiation safety procedures do not indicate the frequency at which surveys will be performed. The application includes statements such as 'smear surveys are made routinely,' 'radiation surveys are made routinely in all laboratory and office areas,' and 'operational surveys are made as needed.'"

CONCLUSIONS

Radioactive material license inspections have shown that the NRC licensing staffs' relying on applicants' qualifications—instead of obtaining and evaluating detailed descriptions of procedures and controls—in determining that applicants understand and are prepared to comply with pertinent regulatory requirements is not appropriate. Many applicants do not translate the requirements into procedures and controls which enable them to operate safely and to comply with the regulations.

By evaluating detailed descriptions of proposed radiation protection procedures and controls, the licensing staff can be better assured that licensees will start and operate their programs safely, particularly between licensing actions and inspections.

It also appears that State programs suffer from the same deficiencies as does the NRC program. NRC needs to help States to encourage them to make similar improvements in their programs. Before entering into new agreements with other States, NRC should insure that State licensing

policies and practices are compatible with NRC's revised licensing program. Extending licensing improvements to the States is especially important because

- --States presently regulate more than half of all radioactive material licensees and
- --NRC is making an intensified effort to transfer regulatory authority for most of the remaining NRC licenses to new agreement States.

RECOMMENDATIONS

We recommend that the Chairman of NRC direct the licensing staff to systematically obtain and evaluate detailed descriptions of applicants' proposed procedures and controls, to help them to start and operate their programs safely and to comply with regulatory requirements.

We recommend also that, in accordance with revisions to its own licensing policies and practices, NRC help States to make similar improvements and, before entering into new agreements, insure that the States' licensing policies and practices are compatible with NRC's revised program.

AGENCY COMMENTS AND OUR EVALUATION

NRC agreed to examine the degree of reliance placed on users' qualifications, to insure a proper balance between applicants' qualifications and the degree of detail required on applications concerning radiation safety controls and procedures. NRC said it would take up this matter with the agreement States in its review of their regulatory programs.

NRC's examination of the degree of reliance placed on applicants' qualifications should lead to greater emphasis on getting and evaluating detailed radiation safety procedures in applications for medical and academic licenses than was the case at the time the licenses we reviewed were issued.

CHAPTER 3

NEED FOR MORE EFFECTIVE COORDINATION

OF LICENSING AND INSPECTION ACTIVITIES

NRC's licensing and inspection activities should be complementary to provide the most effective program.

NRC should make better use of inspection results to evaluate the adequacy of individual licenses and the effectiveness of licensing policies and procedures. Although the licensing staff receives copies of inspection reports and licensee responses to these reports, the licensing staff does not

- --routinely consider inspection results before issuing license amendments or
- --use overall inspection results to help identify areas needing improvement.

Communication between the separate licensing and inspection staffs is essential for an effective program. Present communication between the licensing and inspection staffs is generally limited to informally discussing specific licenses and exchanging copies of licenses and related applications and correspondence, inspection reports, and licensee responses.

According to inspectors, some major weaknesses have not been brought to the licensing staff's attention because it is easier for them to work directly with licensees to strengthen programs than to use a cumbersome communication system to ask the licensing staff to implement more specific license requirements.

The need for the licensing staff to have inspection results when considering licensing actions and the need for closer communication between the inspection and licensing staffs are especially great because of NRC's limited inspection capability and the increasing record of violations.

The fiscal year 1975 budget stated that:

"During FY 1974, staffing levels will be insufficient to maintain even minimal inspection programs. Over 7,500 of 8,500 licenses will not be inspected during FY 1974 and most have not been inspected since the original license was issued. An increase of 30 percent in the number of inspections is

projected in FY 1975 with the special emphasis on radiographers, where problems have been encountered. Also, sampling of the low priority licenses will be undertaken."

The increasing frequency of noncompliance in material license inspections justified the concerns inspection officials expressed. NRC inspectors found violations in 334--33 percent--of 1,009 fiscal year 1971 inspections. This percentage increased each year thereafter to 53 percent in fiscal year 1974 and 56 percent in the first half of fiscal year 1975.

LICENSING STAFF SHOULD CONSIDER PRIOR INSPECTIONS WHEN EVALUATING LICENSE AMENDMENTS

The licensing staff does not routinely consider prior inspections when evaluating applications for license amendments to determine whether previous violations indicating weaknesses in licensees' procedures or controls might be strengthened by licensing actions.

The licensing staff does not believe it needs to systematically review inspection reports. It views individual cases of noncompliance as matters to be dealt with by the inspection and enforcement staff. A staff member said that his responsibility in evaluating amendment applications is the same as when he evaluates initial applications; that is, to determine whether the applicant is qualified to possess and use the requested materials for the proposed purposes. He said the applicant's compliance history does not enter into such a determination. It appears to us that a licensee's past record is critical in determining its acceptability for license amendments.

Regional inspectors agreed. For example, in a memorandum to one regional director of inspection and enforcement, the official responsible for license inspections said that "Licensees with poor compliance histories should not be issued amendments authorizing more activity without first making the necessary corrections in their existing program." The director of the region agreed and emphasized to NRC's inspection headquarters that "reevaluating such areas as licensing requirements and inspection goals to make sure they are consistent with our inspection findings is essential to ensure maximum public safety."

The following example shows the need for the licensing staff to require licensees to correct their programs before

it issues amendments authorizing additional radioactive materials. In a September 1973 inspection, a licensee was cited for 10 violations. The inspection report documented

- ---two instances of radiation exposure or release of radioactive materials in excess of permissible limits,
- --failure to secure licensed materials against unauthorized removal from storage, and
- -- the inspection region's concern about the apparent ineffectiveness of the licensee's management control system that allowed the violations to occur.

After the inspection, the licensing staff issued--at the licensee's request--six amendments, including authorization to possess and use five additional radioactive materials.

The licensing staff stated that neither the inspection report nor the licensee's reply to the report were used in evaluating these amendment applications. They added that the amendments:

"* * * were for routine radiopharmaceuticals and procedures that represented little or no change in the scope of the program, and there would, therefore have been no apparent reason to consult the compliance file prior to issuance of these amendments."

The inspection showed that, even if the program scope had not significantly changed, the licensee was not safely operating its existing program.

A January 1974 reinspection of the licensee showed seven violations, including two recurrent violations. The inspection region again requested the licensee to describe actions taken to improve its management control systems. This inspection report was issued while the licensing staff was authorizing the use of additional radioactive materials.

LICENSING STAFF SHOULD USE INSPECTION RESULTS TO IDENTIFY AREAS NEEDING IMPROVEMENTS

Licensing officials stated that:

"* * * it has been our practice to review all inspection reports as they are forwarded to us with the objective of identifying issues that appear to be generic in nature so that appropriate measures can be taken to avoid their future occurrence, either through licensing guides, license conditions or changes to the regulations."

There was, however, no systematic procedure for compiling such reports. Such a compilation would have been useful to officials in identifying licensees or types of licenses requiring stronger actions. This has led to a lack of awareness of overall regulatory problems. For example, licensing officials were not aware of the extent of radiation survey violations.

Information is available on inspection results that would be useful in identifying areas where stronger licensing provisions might help improve regulatory compliance. The inspection staff has developed a computerized information system to record inspection results. At our request, a number of reports were generated providing statistical summaries of inspection results by type of license, violation, etc. We used these reports to identify areas where licenses could be strengthened to improve the overall program.

Such information could be useful to the licensing staff in evaluating its program. The information system could be of particular use in identifying violation-prone areas needing strengthened license provisions.

At the completion of our review, the inspection staff was in the process of refining its information system for use in evaluating the inspection program. Inspection and licensing officials plan to discuss the feasibility of using the system to help evaluate the licensing program.

WEAKNESSES NOT COMMUNICATED TO LICENSING STAFF

NRC inspectors have identified weaknesses in the program which they believe could be strengthened through improved licensing practices, but they have not effectively communicated this to the licensing staff. Although each weakness is closely related to NRC's basic licensing policy, the weaknesses are more restrictive in that each relates to a particular type of material license or a specific aspect of the program. These weaknesses include

--expansion in the scope of licensed activities without developing commensurate procedures and controls,

- --weak management control systems in radiography programs, and
- --violations of accepted radiation-safety practices.

Expansion of licensed activities

Inspectors told us that, as licensees' requirements for radioactive materials increase and licenses are amended authorizing such increases, radiation protection programs often are not adequately adjusted to handle the increase.

For example, in July 1972 an industrial firm was licensed to possess and use large amounts (10 curies 1/ each) of two radioactive materials and small amounts (5 millicuries 2/ each) of two others. The procedures and controls described in the application were either incomplete or very general.

In March 1973 the licensee requested and received authority to increase the 10-curie-possession limit of the two materials to 50 curies each. The licensee did not describe--nor was he required to describe--the procedures or controls to be used as a result of the fivefold increase in the possession limit.

In the initial inspection made in September 1973 the licensee was cited for seven violations, four of which, if not corrected, were important enough to possibly result in excessive radioactivity. The inspection staff expressed its concern over the licensee's management control system which permitted the violations to occur.

During April and May 1974 the licensee requested and received authority to further increase the possession limit of the two 10-curie materials from 50 to 75 curies each. Again no additional information on procedures or controls was required, even though the authorized possession limit had been increased by 7-1/2 times the original quantities and inspectors had expressed concern over the adequacy of the licensee's management controls.

A January 1975 inspection revealed seven violations, including four incidents of overexposure to two persons

^{1/}An amount of any radioactive material which disintegrates at the rate of 3.7 x 10^{10} disintegrations per second.

^{2/}One-thousandth of 1 curie.

and failure to survey radiation levels in unrestricted areas. Again the inspection staff expressed its concern to the licensee:

"* * * about the need for a more comprehensive radiation safety program and about the need to correct the weaknesses in * * * [the licensee's] * * * management control systems that allowed the violations to occur."

Following the second inspection, the inspection staff telephoned the licensing staff to

- --emphasize that the licensee had a poor inspection record and its radiation safety program was marginal;
- --express its concern that, in spite of the poor radiation safety program, the program kept expanding; and
- --inform the licensing staff that it should "tighten up" on the licensee's program.

In July 1975 the license was amended to increase the possession limits of the two materials to 125 curies each. Again no additional procedures or controls were described or required.

Of the 36 licenses we reviewed, 22 had been amended to expand the scope of the licenses by adding types, quantities, and physical or chemical forms of radioactive materials or by adding additional users. In fiscal year 1974 inspections, 19 violations found in 7 of the 22 licenses reviewed were directly related to the new program scope.

Weak management controls in radiography programs

Because of the relatively high potential radiation hazards in radiography programs, applicants are required to develop and carry out well-defined operating and emergency procedures. NRC's licensing staff requires radiography applicants to describe, in detail, their organizational structures, operating and emergency procedures, radiographic training programs, recordkeeping procedures, and equipment maintenance programs.

Although the 55-percent rate for noncompliance in radiography inspections is lower than for medical and academic license inspections, the rate is still high. (See table on p. 11.)

Inspection officials believe that these programs need a commitment by management to radiation protection, as demonstrated by effective controls, to insure that workers follow all prescribed operating and emergency procedures. They believe that NRC's licensing activity could help strengthen programs by requiring applicants to develop and describening addition to detailed operating procedures—all the management controls to be used in insuring that operating procedures are followed.

Of the 36 licenses we reviewed, 5 were radiography licenses. In fiscal year 1974 inspections of these licenses, inspectors found 14 major violations of regulations and license conditions. Some violations were the same, or similar, to violations found in previous inspections of these licenses.

For example, for one license issued in 1971, the licensing staff had requested, and the applicant had provided, descriptions of procedures for routine operations, including radiation safety, equipment inspection and maintenance, and emergency situations.

In 4 inspections of this license--the last conducted in February 1974--inspectors found 15 violations, including recurring violations related to inspection and maintenance of equipment and maintenance of radiation exposure records.

The inspection violations—as inspectors state in correspondence with the licensee—relate to management's failure to establish controls to insure that all personnel follow prescribed procedures. NRC inspectors told us that the licensing staff could have been of assistance (and could be for all future radiography licenses) by requiring applicants, in their applications, to provide information

- --demonstrating that their radiation safety officers were capable of effectively carrying out their assigned responsibilities by describing how they would carry them out and
- --describing the methods management would use, including written reports documenting problems identified and their disposition, to evaluate the radiation safety officers.

Violations of accepted radiation safety practices

Inspectors sometimes find licensees following procedures which are unsafe but not specifically prohibited by NRC's

regulations or by license conditions. In these instances, inspectors cite licensees for violations of generally accepted radiation-safety practices--safety violations. NRC can suspend, modify, or revoke licenses, or impose civil penalties for violations of regulations and license conditions, but not for safety violations.

Inspectors stated that safety violations usually indicated a need to condition a license by requiring or prohibiting certain actions. Conditioning the license gives enforcement power to inspectors to insure that a licensee takes adequate corrective measures.

Inspectors had cited 10 of 36 licensees reviewed for 13 safety violations. For example, an inspector found that a licensee was storing radioactive wastes in an area where open-top drums filled with leaking vials of a flammable liquid also were being stored. This violated the safety practice of properly controlling flammables stored near radioactive materials, to minimize fire danger. Because the condition was not addressed in NRC's regulations or in the license, the inspector could not cite the licensee for a regulation or license violation.

We asked the licensing staff if, after the inspection, the license should have been amended to incorporate the licensee's proposed corrective action. The licensing staff said it considered the corrective action to be binding on the licensee and that therefore a specific license condition was not necessary.

We found, however, that some licensees failed to carry out their proposed corrective actions. For example, safety violations were noted in December 1973 inspections of a licensee holding two licenses. In September 1974--9 months later--the licensee was reinspected and the same safety violations were found. Since the licenses had not been amended to require the proposed corrective actions as conditions of the licenses, the inspector again cited the licensee for safety violations. Had the licenses been conditioned, the inspector could have cited the licensee for violating license conditions and could have taken enforcement actions.

CONCLUSIONS

NRC's regulatory program could be improved by more effective communication and coordination between the licensing and inspection staffs. Inspection results could be more effectively used to determine the adequacy of

individual licenses and of licensing policies and practices. Inspection results on individual licenses are not effectively used to help correct regulatory problems, nor are they effectively used, in the aggregate, to help identify common regulatory problems which might be corrected by stronger licensing actions.

RECOMMENDATIONS

We recommend that the Chairman of NRC direct the licensing staff to establish procedures to

- --routinely consider inspection results before amending or renewing licenses and
- --use inspection results to systematically identify generic inadequacies in licensed programs that may be strengthened through the licensing process.

We recommend also that the Chairman of NRC direct the licensing and inspection staffs to establish more effective channels of communication to promote a more open exchange of information regarding program improvements.

AGENCY COMMENTS

Although NRC did not outline the specific corrective actions being taken, it did state that steps were being taken to insure

- --systematic review of inspection findings before taking important licensing actions,
- -- analyses of composite inspection findings to identify and correct licensing-related generic problems, and
- --continuing coordination of licensing and inspection activities.

CHAPTER 4

NEED FOR STANDARD LICENSE REVIEW AND

MANAGEMENT EVALUATION PROGRAMS

Licensing staff members are not required to document the reasons for their decisions, although this would make for consistent and complete licensing reviews, assist other license reviewers in evaluating license amendments and renewals, and assist management officials in evaluating the appropriateness of licensing actions.

The process for documenting licensing decisions should be under a standard license review program which would identify whether all pertinent aspects of proposed programs were considered during licensing reviews. In addition, management officials should establish a systematic review program for evaluating the appropriateness of licensing actions.

NEED TO ESTABLISH BASES FOR LICENSING ACTIONS

In designing proposed programs, applicants are required to develop procedures and controls adequate for insuring their ability to safely handle and use radioactive materials.

To assist the licensing staff members in evaluating license applications, NRC has issued an internal guide to licensing procedures. For the major types of licenses (medical, academic, etc.), the guide identifies the aspects of proposed programs which should be considered in evaluating applications. For example, for academic license applications, the guide lists the following radiation protection and administrative control aspects which should be evaluated.

- --Equipment and facilities available and the procedures used for receipt, storage, security, or shipment of materials.
- --Laboratory facilities and equipment for processing and handling uncontained radioactive materials.
- --Waste disposal procedures.
- --Instructions to students and laboratory and custodial personnel regarding emergencies, spills, and handling procedures.

--Control procedures to be used in the movement of materials from storage to their place of use in the institution, including required recordkeeping and accountability for materials.

Applicants frequently did not describe in their applications the procedures and controls to comply with NRC's regulations, and the licensing staff did not require such descriptions.

Decisions on which procedures and controls must be described and the detail of those descriptions were made by license reviewers on the basis of their professional judgments. NRC licensing officials stated that this was necessary and appropriate because of the diversity in scope of proposed programs.

Licensing staff members did not, however, systematically document in the license files what aspects of applicants' proposed programs were considered or the degree to which they were considered in determining

- --whether applications were adequate and sufficiently complete to warrant issuing licenses and license amendments and
- --why complete descriptions of procedures and controls were not considered necessary in their evaluations.

The reasons why staff members did not require applicants to completely describe proposed procedures and controls were not documented for the 36 licenses we reviewed.

The bases for the judgments of the license reviewers on the nature and detail of information necessary for properly evaluating applications should be systematically documented in order to

- --insure consistent and complete licensing reviews,
- --assist other staff members in evaluating license amendments and renewals, and
- --assist licensing management in evaluating the appropriateness of licensing actions.

Due to the variances in program scopes, even among similar types of licenses, there is a need to provide a mechanism for insuring that applications are consistently and completely reviewed.

In responding to our questions on 10 licenses, the licensing staff agreed that additional descriptions of radiation protection procedures and controls should have been required for proper evaluation of two licenses. However, the reasons for not requiring the additional information were not documented in the license files.

Most of the applications the licensing staff processes are for amending or renewing existing licenses. The staff member reviewing an amendment or renewal application may not be the same staff member who evaluated the initial application and issued the license.

To broaden the experience of the licensing staff, officals have established a policy of periodically assigning all but designated senior staff to reviews of different types of licenses. Although this policy provides staff members with diversified experience, it also increases the probability of amendment and renewal applications' being evaluated by different staff members who would not have documentation of the determinations made in issuing the basic licenses.

Information on the basic license would permit a more thorough review of amendment and renewal applications. During our work we found it necessary to discuss licensing actions with reviewers to find out how certain aspects of applicants' programs were evaluated and to determine the basis for licensing decisions.

In several instances the license reviewer presently administering the license could not explain the bases for these licensing decisions and acknowledged that information in the license file might not be adequate to support the decisions.

The licensing staff has not established procedures for systematically reviewing the propriety of licensing actions.

Authority to directly issue licenses has been delegated to 11 of the 13 staff members. A senior staff member said that the review usually stops with a person who is authorized to sign the license, which results in most licenses being issued without any other review.

Officials told us that senior staff members periodically reviewed the work of junior members. One senior staff member said his review of junior staff members' work was limited

to policy questions. He added that, except for these policy matters, each member of the licensing staff was responsible for his own work.

CONCLUSIONS

There is no efficient way, short of a complete reevaluation of an application, to determine the completeness, consistency, and general propriety of a licensing review, because NRC does not require a license reviewer to document the bases for his licensing decision.

As discussed in chapter 2, NRC's licensing staff should require applicants to describe their proposed procedures and controls for insuring that they will comply with all NRC requirements. The adequacy of these procedures and controls for the proposed programs, along with applicant's training and experience, facilities, and equipment, should be considered in evaluating applications.

A standard license review program that provides for documentation of the bases for licensing decisions would provide for more consistent and complete evaluations of license applications, assist in reviewing amendment and renewal applications, and assist licensing officials in evaluating the appropriateness of licensing actions.

Such a program would be an effective tool for insuring that all aspects of proposed programs are described by applicants and considered by reviewers before licenses are issued. All aspects of major types of licensed programs that should be considered in evaluating applications would be identified for the license reviewers who would document the consideration given to each aspect. Such documentation would then be available to other reviewers who evaluate amendment and renewal applications and to supervisory reviewers and licensing officials who evaluate the propriety of licensing actions.

RECOMMENDATION

We recommend that the Chairman of NRC direct the licensing staff to establish a standard review program for evaluating material license applications and the propriety of licensing actions.

AGENCY COMMENTS AND OUR EVALUATION

NRC noted that measures in effect which met the objective of our recommendations included

- --staff utilization of the licensing guides, which specify to applicants the type of information applications must contain, in reviewing applications and
- --monitoring the quality and uniformity of the license review process by supervision.

NRC also noted that existing licensing guides were being revised and updated and that new guides were being prepared for certain areas of radioactive materials use where guides did not exist previously.

Use of the new and revised guides by the licensing staff is an acceptable alternative to establishing standard review plans if (1) staff members are specifically directed to adhere to the information requirements stated in the guides and (2) licensing management systematically reviews completed licensing actions to insure that information requirements identified in the guide were met before licenses were issued.

CHAPTER 5

SCOPE OF REVIEW

We reviewed NRC's policies, procedures, and practices for licensing radioactive material users. We made our review at NRC's headquarters in Bethesda, Maryland, and at its inspection and enforcement office in King of Prussia, Pennsylvania.

We examined records, reports, licensing guides, and correspondence relating to the licensing staff's review and evaluation of license applications. In addition, we examined selected material license and inspection files and inspection and enforcement correspondence and interviewed both head-quarters and regional officials and staff responsible for material licensing, inspection, and enforcement.

We also examined recent evaluations of State programs, to identify problems encountered by States in licensing radioactive material users.

UNITED STATES NUCLEAR REGULATORY COMMISSION WASHINGTON, D. C. 20555

Mr. Henry Eschwege, Director Resources and Economic Development Division U.S. General Accounting Office Washington, D.C. 20548

Dear Mr. Eschwege:

We have reviewed the draft report entitled "Need for Improved Licensing of Radioactive Materials Users," and have the following comments:

We do not agree that the citation and analysis of the individual material licensing cases selected by GAO are indicative of the licensing program. However, we do agree with GAO concerning the need to examine the degree of reliance placed on applicants' qualifications and to factor inspection findings into the license review process.

Therefore, although we do not believe the report provides a basis for drawing conclusions about the overall quality of the licensing program as it relates to public health and safety, we will reexamine the degree of reliance being placed upon user qualifications in order to assure a proper balance between the applicant's qualifications and the degree of detail required in the application concerning radiation safety controls and procedures. This is a matter of good regulatory practice. The examination will take into account the inspection findings with respect to materials licensees. Such an examination has, in fact, been taking place on a continuing basis, and, as a result, more emphasis is currently being placed on detailed radiation safety procedures in applications for medical and academic licenses than was the case at the time that the licenses reviewed by the GAO staff were issued (over 2 years ago). This matter will be taken up with the Agreement States in connection with our review of their regulatory programs.

With respect to the relationships between the licensing and inspection staffs, steps have already been taken to assure (a) a systematic review of inspection findings prior to taking significant licensing actions, (b) analyses of composite inspection findings to identify and correct generic problems which can be dealt with

Mr. Henry Eschwege

- 2 -

through the licensing process, and (c) continuing coordination of licensing and inspection activities.

With regard to GAO comments about the uniformity and completeness of licensing reviews, measures which are in effect to meet these objectives include (a) staff utilization of licensing guides, which specify the type of information applications must contain, in conducting licensing reviews, and (b) monitoring of the quality and uniformity of the license review process by supervision. Existing licensing guides are being revised and updated and new guides are being prepared for certain areas of material use where guides did not exist previously.

In summary, we recognize that the continued protection of the public health and safety must be assured, and responsibility does not end with the issuance of a license. We believe the necessary assurance can best be provided by maintaining the proper balance in the NRC regulatory program between standards, licensing, inspection and enforcement. We are continually examining this balance and making appropriate adjustments in keeping with inspection findings and with changes in radioisotope utilization and radiation protection policies.

Sincerely,

Lee V. Gossick

Executive Director for Operations

APPENDIX II APPENDIX II

PRINCIPAL MANAGEMENT OFFICIALS

RESPONSIBLE FOR ADMINISTRATION OF ACTIVITIES

DISCUSSED IN THIS REPORT

| | Tenure of office | | | | | |
|---|------------------|--------------|-------|------|--|--|
| | F | rom | | To | | |
| ATOMIC ENERGY COMM | ISSION | | | | | |
| CHAIRMAN: | | | | | | |
| Dixy Lee Ray James R. Schlesinger | | 1973 1971 | | | | |
| DIRECTOR OF REGULATION: L. Manning Muntzing | Oct | 1971 | Jan. | 1975 | | |
| 1. Maining Mancaing | 000. | 17,1 | oun. | 17,3 | | |
| DIRECTOR, DIRECTORATE OF LICENSING: | | | | | | |
| Edson G. Case (acting) | | 1974 | | 1975 | | |
| John F. O'Leary | July | 1972 | June | 1974 | | |
| DIRECTOR, DIRECTORATE OF REGULATORY OPERATIONS: | | | | | | |
| Donald F. Knuth | | 1973 | | | | |
| Frank E. Kruesi | July | 1972 | July | 1973 | | |
| NUCLEAR REGULATORY COMMISSION | | | | | | |
| CHAIRMAN: | | | | | | |
| William A. Anders | Jan. | 1975 | Prese | nt | | |
| EXECUTIVE DIRECTOR FOR OPERA- | | | | | | |
| Lee V. Gossick | Mar. | 1975 | | nt | | |
| Lee V. Gossick (acting) | Jan. | 1975 | Mar. | 1975 | | |
| DIRECTOR, OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFE- GUARDS: | | | | | | |
| Kenneth R. Chapman | | 1975 | | nt | | |
| Howard J. Larson (acting) | Jan. | 1975 | Mar. | 1975 | | |
| DIRECTOR, OFFICE OF INSPECTION AND ENFORCEMENT: | | | | | | |
| Donald F. Knuth | Jan. | 1975 | Prese | nt | | |

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